

K970757
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Appendix E : Summary of Safety and Effectiveness Data

General Information and Description

The Fotona Skinscan system is a microprocessor controlled device which generates precisely defined patterns on skin tissue in an automated sequence to increase uniformity and ease of treatment when used in conjunction with a host Skinlight system.

The Fotona Skinscan system is designed as an accessory for use with the Fotona Skinlight laser system. Skinscan is functionally integrated to the host laser system. When the scanner head is attached to the articulated arm and the scanner cable is connected, the host laser system recognizes the presence and activation of the accessory and permits activation of the scanner specific modes which are programmed into the host at time of installation of the scanner accessory. In these modes scanner settings can be selected from an easy-to-read menu. When the operator reverts to use of the standard dermatological handpiece, these settings are not accessible. When the scanner is connected and a scanner sub-menu is selected the system automatically initiates for scanner operation.

The Skinscan system is designed with 3 major sub-systems

- a) A scanner handpiece comprising smoke evacuation components and distance gauge components.
- b) A scanner head, containing scanning mirrors and imaging optics.
- c) An electronic control box containing scanning mirror control and laser interface circuitry.

No accessories are available for use with Skinscan

Summary of Substantial Equivalence

Fotona believes that its Skinscan system is substantially equivalent to the Coherent CPG system, previously cleared under K 946304.

Technologically, the predicate has identical characteristics to Skinscan, both comprising an electronic control module, a scanner head and a scanner handpiece.

Both devices act as accessories to host laser systems and are not themselves active components.

It is therefore believed that there are no new questions of Safety or Effectiveness raised by the introduction of this device.